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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,586

09/09/2004

Bum-Joon Kim

038779/280277

7698

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7590

01/07/2009

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/500,586

**Applicant(s)**

KIM ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 8-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 15, 16 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5 and 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' Response to Office Action, received 10 October 2008, is acknowledged.
2. Claims 1-5 and 8—6 are pending and under consideration.

**Rejections Withdrawn**

3. The rejection of claims 1-5 and 8-16 under 35 U.S.C. 112, second paragraph, as being indefinite for "gene fragment" is withdrawn.

**Claim Rejections - 35 USC § 112**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a polynucleotide "of an hsp 65 gene fragment". This language encompasses a sequence of 2 or 3 nucleotides. It is unclear what function such a polynucleotide entails.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a polynucleotide set wherein the set consists of "at least" an hsp 65 gene fragment selected from a group of SEQ ID NOs and complementary polynucleotides thereto.

It is unclear how one has a "set" if only one sequence is chosen.

7. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method for identification of mycobacterial species comprising: (1) amplifying an hsp 65 gene, (2) analyzing a nucleotide sequence of the amplified hsp 65 gene fragment, and (3) aligning the sequence with a polynucleotide set wherein the set consists of "at least" an hsp 65 gene fragment selected from a group of SEQ ID NOs and complementary polynucleotides thereto, to infer a phylogenetic tree.

It is unclear what steps are involved in "analyzing" a nucleotide sequence.

It is unclear how one has a "set" if only one sequence is chosen.

It is unclear what is meant by "infer a phylogenetic tree".

8. Claims 1, 2, 5 and 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in light of applicants' remarks in the instant response.

The claims are drawn to a method of identification of mycobacterial species by amplifying an hsp 65 fragment of mycobacterial species with primers consisting of SEQ ID NO:55 and SEQ ID NO:56, "wherein the 644-bp hsp 65 gene fragment" is not cleaved.

Applicants' Remarks, page 2, paragraph 4, states that the primers SEQ ID NO:55 and SEQ ID NO:56 would not amplify the entire hsp 65 gene, but "only 604-bp hsp 65 gene fragment".

Thus, it is unclear what the size of the fragment would be in the claims because of the discrepancy in size between what is claimed and applicants' remarks.

### **Conclusion**

9. Claims 1, 2, 4, 5 and 8-14 are rejected.
10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./  
Primary Examiner, Art Unit 1645  
January 1, 2009